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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,950	05/19/2006	Yukihiko Uchi	P28510	6546

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EXAMINER	
ZALASKY, KATHERINE M	
ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
12/12/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
pto@gbpatent.com

Office Action Summary	Application No.	Applicant(s)	
	10/553,950	UCHI ET AL.	
	Examiner	Art Unit	
	KATHERINE ZALASKY	4153	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20070910, 20060215*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 20 April 2006 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

Specification

2. The abstract of the disclosure is objected to because it is longer than 150 words and is not limited to a single paragraph. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1 and 11-13** are rejected under 35 U.S.C. 102(b) as being anticipated by Fukasawa et al. (EP 0306613).

Regarding **claim 1**, Fukasawa et al. discloses a hollow fiber membrane type fluid treatment device (pg 3, L19-22) comprising:

- at least a body portion of tubular housing (15) containing a hollow fiber membrane bundle (17)
- a housing head portion (29) which is connected with one end of the housing body portion and has a resin layer (19) where the hollow fiber membrane bundle is fixed by using a resin composition (pg 6/L16-25) and a connection port (27) which serves as a treatment liquid inlet
- a housing head portion (30) which is connected with the other end of the housing body portion and has a resin layer (18) where the hollow fiber membrane bundle is fixed by using a resin composition (pg 6/L16-25) and a connection port which serves as a treatment liquid outlet (28)
- header caps (20, 21) attached to these housing head portions and having a treatment target liquid connection ports (23, 25), respectively
- characterized in that the fluid treatment device has at least a diameter-expanding portion which is provided to an inner surface of a treatment liquid inlet side in the tubular housing and enables the hollow fiber membranes to be disposed so that a distance between the hollow fiber membranes is gradually increased toward an end face of the treatment liquid inlet side (Figure 3 & pg 5/L22-33)

Regarding **claim 11**, Fukasawa et al. discloses all of the claim limitations as set forth above. Additionally, the reference discloses the device wherein the diameter-

expanding portion comprises an end tapered portion which increases in diameter toward the end face of the housing body portion (Figure 3) and the inner surface of the housing body portion on the treatment liquid inlet side includes a body straight portion (Figures 3-4, straight portions on the inner surface, near to ports 27 & 28).

Regarding **claim 12**, Fukasawa et al. discloses all of the claim limitations as set forth above. Additionally, the reference discloses the device wherein the hollow fiber membrane bundle is arranged so that the distance between the hollow fiber membranes is gradually increased toward the end face on the treatment liquid inlet side along a taper of a tapered portion of the inner surface of the housing body portion (Figure 3, P 5/L22-33).

Regarding **claim 13**, Fukasawa et al. discloses all of the claim limitations as set forth above. Additionally, the reference discloses the device wherein the tapered portion comprises:

- a first tapered portion located on the body portion side (Figure 3, tapered portions by passages 29 & 30)
- a second tapered portion located on the treatment liquid inlet side (Figure 3, tapered portions by ports, 27 & 28)
- the angle of the first taper angle is smaller than the angle of the second taper angle (Figure 3, pg 4/L57 – pg 5/L2)

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. **Claims 14 and 16-17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukasawa et al. (EP 0306613), as applied to **claim 1** above.

Regarding **claim 14**, Fukasawa et al. discloses all of the claim limitations as set forth above, but does not explicitly disclose the device wherein an angle formed by a centerline of the inner surface of the housing body portion and an inner surface of the end tapered portion is greater than 0° and smaller than an angle defined by $\tan^{-1}$

{(1/2)•(d1-d4)/L4}. As the packing density and thus the efficiency of treatment fluid exchange are variables that can be modified, among others, by adjusting said angle, the precise angle would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made (see pg 5, L25-28). As such, without showing unexpected results, the claimed angle cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the angle in the apparatus of modified Fukasawa to obtain the desired packing density and efficiency (In re Boesch, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223).

Regarding **claim 16**, Fukasawa et al. discloses all of the claim limitations as set forth above. While the reference does not explicitly disclose the ratio of the length of the body straight portion to the total length of the end tapered portion being between 0.7 to 20 and the ratio of the inner diameter of the end tapered portion on the end face side to the inner diameter of the body straight portion being more than 1 and not more than 3, since the instant specification is silent to unexpected results, it would have been obvious to one of ordinary skill in the art to change the lengths of the tapered and straight body portions as well as the diameters, since such a modification would have involved a mere change in the size (or dimension) of a component. A change in size (or dimension) is generally recognized as being within the level of ordinary skill in the art. In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). Where the only difference

between the prior art and the claims is a recitation of relative dimensions of the claimed device, and the device having the claimed dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device, Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

Regarding **claim 17**, modified Fukasawa discloses all of the claim limitations as set forth above. Regarding limitations recited in **claim 17** which are directed to a manner of operating disclosed device (e.g. "a urea clearance of 191 to 200 ml/min"), it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See Ex parte Thibault, 164 USPQ 666, 667 (Bd. App. 1969) that states "Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim."

9. **Claims 2-10, 15 and 18-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukasawa et al. (EP 0306613), as applied to **claims 1 and 11** above, and further in view of Kanno et al. (US 4,201,673).

Regarding **claim 2**, Fukasawa et al. discloses all of the claim limitations as set forth above. The reference does not explicitly disclose the device wherein the diameter-expanding portion comprises a baffle plate provided at a position corresponding to the treatment liquid inlet of the tubular housing and interspatially from an inner

circumference of the tubular housing over the entire inner circumference at a curvature almost along the inner circumference, and the baffle plate gradually increases in diameter toward the end face of the housing.

Kanno et al. discloses a dialyzer with hollow fiber membranes (abstract) which contains a baffle plate (annular rib 15) which increases in diameter toward the end of the housing (see Figures 2 & 3). Kanno et al. teaches that a baffle plate may help avoid channeling and may improve efficiency by allowing the dialysate to flow over the outermost hollow fibers (C1/L45-60).

Fukasawa et al. and Kanno et al. are analogous because both references are directed to hollow fiber membrane modules.

It would have been obvious to one having ordinary skill in the art at the time of the invention to add a baffle plate to the dialyzer of Fukasawa et al., as taught by Kanno et al., since doing so may help avoid channeling, thereby improving the efficiency of the device.

Regarding **claim 3**, modified Fukasawa discloses all of the claim limitations as set forth above. Additionally, Kanno et al. discloses the device wherein the hollow fiber membrane bundle is arranged so that the distance between the hollow fiber membranes is gradually increased toward the end face on the inlet side along the increased diameter of the baffle plate (Figure 2, hollow fibers flare outward at ends).

Regarding **claim 4**, modified Fukasawa discloses all of the claim limitations as set forth above. Additionally, Kanno et al. discloses the device wherein the end portion

of the baffle plate has a shape curved along the circumference inside the resin layer (Figure 2, annular rib 15 follows the circumference of the housing).

Regarding **claims 5-6**, modified Fukasawa discloses all of the claim limitations as set forth above, but does not explicitly disclose the device wherein an angle formed by the centerline of the tubular housing and the inner circumferential surface of the baffle plate is greater than 0°, or greater than 1°, and smaller than the angle defined by $\tan^{-1}\{(1/2)\bullet(d1-d3)/L3\}$. As the packing density and thus the efficiency of treatment fluid exchange are variables that can be modified, among others, by adjusting said angle, the precise angle would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made (see pg 5, L25-28). As such, without showing unexpected results, the claimed angle cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the angle in the apparatus of modified Fukasawa to obtain the desired packing density and efficiency (In re Boesch, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223).

Regarding **claim 7**, modified Fukasawa discloses all of the claim limitations as set forth above. While modified Fukasawa does not explicitly disclose the height of the baffle plate, since the instant specification is silent to unexpected results, it would have been obvious to one of ordinary skill in the art to change the height of the baffle plate, since such a modification would have involved a mere change in the size (or dimension)

of a component. A change in size (dimension) is generally recognized as being within the level of ordinary skill in the art. In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). Where the only difference between the prior art and the claims is a recitation of relative dimensions of the claimed device, and the device having the claimed dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device, Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

Regarding **claims 8-9**, modified Fukasawa discloses all of the claim limitations as set forth above. Regarding limitations recited in **claims 8-9** which are directed to a manner of operating disclosed device (e.g. "a urea clearance of 191 to 200 ml/min"), it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See Ex parte Thibault, 164 USPQ 666, 667 (Bd. App. 1969) that states "Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim."

Regarding **claim 10**, modified Fukasawa discloses all of the claim limitations as set forth above. Additionally, Fukasawa et al. discloses the device wherein at least the inner surface of the housing body portion on the treatment liquid inlet side comprises:

- a body straight portion (Figure 3, straight portions next to ports 27 & 28)

- an end tapered portion which increases in diameter toward the end face of the housing body portion (Figures 3-4)

Regarding **claim 15**, Fukasawa et al. discloses all of the claim limitations as set forth above, but does not explicitly disclose the device wherein an angle formed by a centerline of the inner surface of the housing body portion and an inner surface of the end tapered portion is greater than 0.58° and smaller than an angle defined by $\tan^{-1}$ {(1/2)•(d1-d4)/L4}. As the packing density and thus the efficiency of treatment fluid exchange are variables that can be modified, among others, by adjusting said angle, the precise angle would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made (see pg 5, L25-28). As such, without showing unexpected results, the claimed angle cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the angle in the apparatus of modified Fukasawa to obtain the desired packing density and efficiency (In re Boesch, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223).

Regarding **claims 18-19**, Fukasawa et al. discloses all of the claim limitations as set forth above. The reference does not explicitly disclose the device comprising baffle plates provided at positions corresponding to the treatment liquid inlet and the treatment liquid outlet of the tubular housing and interspatially from the inner circumference of the tubular housing over the entire inner circumference at a curvature almost along the

inner circumference. Further, the reference does not disclose the device wherein the baffle plate gradually increases in diameter toward the end face of the housing.

Kanno et al. discloses a dialyzer with hollow fiber membranes (abstract) which contains a baffle plate (annular rib 15) which increases in diameter toward the end of the housing (see Figures 2 &3). Kanno et al. teaches that a baffle plate may help avoid channeling and may improve efficiency by allowing dialysate to flow over the outermost hollow fibers (C1/L45-60).

Fukasawa et al. and Kanno et al. are analogous because both references are directed to hollow fiber membrane modules.

It would have been obvious to one having ordinary skill in the art at the time of the invention to add a baffle plate to the dialyzer of Fukasawa et al, as taught by Kanno et al., since doing so may help avoid channeling, thereby improving the efficiency of the device.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE ZALASKY whose telephone number is (571)270-7064. The examiner can normally be reached on Monday-Thursday, 7:30am - 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Basia Ridley can be reached on (571) 272-1453. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KZ/
3 December 2008

/Basia Ridley/
Supervisory Patent Examiner, Art Unit 4153